EXHIBIT 5

to

PAUL D. BRACHMAN DECLARATION IN SUPPORT OF DEFENDANT'S TRIAL BRIEF

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April 16, 2019

VIA CERTIFIED MAIL & E-mail

David Mixner
Rebotix Repair LLC
6822 22nd Avenue North, Suite 283
St. Petersburg, FL 33710

Subject: Tampering with and Reprogramming *da Vinci*® Surgical System Instruments

Dear Mr. Mixner,

We write on behalf of Intuitive Surgical, Inc. ("Intuitive"), a company that develops and distributes advanced robotic-assisted surgical platforms for minimally-invasive surgery. Our core products include the *da Vinci*® Surgical System (the "System") as well as the *EndoWrist*® instruments that attach to the System.

It has come to our attention that Rebotix Repair LLC ("Rebotix"), either directly or indirectly through its "service centers", is engaging in the unauthorized manufacturing and marketing of a medical device without proper regulatory authorization from the U.S. Food and Drug Administration ("FDA" or the "agency"). We also have concerns that the devices potentially being distributed are not being manufactured, or re-manufactured as the case may be, under a recognized quality management system applicable to medical devices. In addition, we believe that Rebotix and its service center representatives engaged in behavior that violates applicable laws and may give rise to civil liability. We write to you on behalf of Intuitive to demand that Rebotix immediately cease and desist from any and all improper behavior with regard to the *EndoWrist*® instruments, including but not limited to your actions described below.

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Regulatory Background

In the United States, class II medical devices – including *da Vinci*® Systems and *EndoWrist* instruments – are subject to premarket notification clearance, compliance with the Quality System Regulation (QSR), among other regulations promulgated by the FDA to ensure the safety and effectiveness of each medical device over its intended life. With respect to class II devices and related accessories, only those with FDA 510(k) clearance may be placed in the U.S. market. Moreover, it is FDA policy that only one company can manufacture and market a product under a single 510(k) absent a contract manufacturing or private labelling agreement between the parties. Further, any change or modification to a cleared class II medical device that could significantly affect its safety or effectiveness voids the prior 510(k) clearance as to the modified device, rendering its use unlawful without a new clearance. This includes changes to the cleared indications for use.

FDA also imposes strict requirements regarding the design, development and manufacturing of medical devices. These good manufacturing practices are codified in the Quality System Regulation, 21 C.F.R. Part 820. The QSR requires that medical device manufacturers have a quality management system in place for the design, manufacture, packaging, labelling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States. As a key part of compliance with these requirements, device manufacturers must verify and validate both their designs and their manufacturing processes to ensure that they can consistently meet required specifications and user needs, and that such specifications are appropriate to ensure device performance and patient safety. Utilizing these process controls, manufacturers must identify the useful life of their devices, as well as service and maintenance requirements to ensure their safe and effective use. All service and maintenance must be performed per a controlled process and bring products to their FDA cleared specifications. Any changes to these specifications require extensive verification and validation subject to a comprehensive set of quality management procedures. Such changes also may require additional clearance from the FDA.

Importantly, FDA also requires certain refurbishers and service providers to register their establishments with the agency. Specifically, any entity that processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use must register their establishment and list the devices being remanufactured at the subject facility.

Factual Background

In accordance with its quality system, Intuitive engages in rigorous testing prior to submitting its medical devices for FDA clearance. Generally, and specifically with respect to the *EndoWrist*® instruments, that includes instrument reliability/projected life testing to confirm the maximum number of safe and effective clinical uses of a product prior to disposal. Those test results are often incorporated into the FDA 510(k) clearance application. With respect to many of the *EndoWrist*® instruments, Intuitive Surgical determined – and the FDA 510(k) clearance reflects – ten surgical procedures is the maximum number of safe and effective clinical uses prior to disposal. Accordingly, Intuitive placed a memory device inside such instruments that keeps track of the usage count and inhibits the instrument from functioning after ten uses.

We recently have become aware that you are offering Intuitive customers in the United States a service where "[y]our authorized service centers" will "inspect and recondition" *EndoWrist*® instruments to allow the *EndoWrist*® instruments to be used beyond their pre-programmed, cleared number of uses.

Rebotix's Alleged Activities Violate U.S. Law

We have numerous concerns with the foregoing activities. First, it is unclear whether you or your service technicians have the requisite specifications by which to make the claim that the units are returned to their production equivalent qualification. Even assuming for argument that you have obtained these specifications, or Intuitive' s service manual, any modifications that reset or extend the number of uses of the device also violates FDA requirements. This change impacts the intended use of the device, exceeds the verified and validated testing used to support the FDA clearance, and thereby constitutes a major change to the device. This change could significantly affect the safety and effectiveness of the device and therefore requires clearance of a new 510(k). To our knowledge, FDA

has not granted Rebotix or its service centers 510(k) clearance to market or distribute modified *EndoWrist*® instruments in the United States for any indication for use. Thus, it appears that Rebotix and it service centers are manufacturing, marketing, and selling class II medical devices without FDA premarket clearance. As a result, it appears that these activities adulterate under 21 U.S.C. § 351(f)(1)(B) and/or misbrand under 21 U.S.C. § 352(o) the products you and your service centers are entering into commerce, because the law requires, and you and your service centers do not have, a 510(k) clearance showing that the "reconditioned" device is substantially equivalent to a legally marketed predicate device. Moreover, any claims that Rebotix and its service centers are able to market significantly modified versions of Intuitive's *EndoWrist*® instruments also violate FDA's longstanding policy that only one company can manufacture and market a medical device under a single 510(k) absent an agreement between the companies to do so.

Rebotix and its service centers also appear to be marketing these devices without accurate establishment registration and device listing with FDA. Due to the nature and extent of the modifications of the activities apparently being performed, Rebotix or one of its service centers is considered to be a "remanufacturer." FDA defines a remanufacturer as any entity that processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use. As a remanufacturer of medical devices, regardless of whether you hold a 510(k) or not, you are required to register your manufacturing establishment with FDA and to submit a device listing to the agency. 21 U.S.C. §360; 21 C.F.R. § 807.20. Your failure to do so misbrands the remanufactured devices placed into commerce by Rebotix and its service centers. 21 U.S.C. § 352(o).

As previously stated, it does not appear that Rebotix or any of its service centers has the requisite 510(k) clearance to support the remanufacturing, marketing and sale of its services as they may pertain to *EndoWrist*® instruments. Consequently, any such Intuitive products placed into commerce by Rebotix or its service centers are likely adulterated under 21 U.S.C. § 351(f)(1)(B) and/or misbranded under 21 U.S.C. § 352(o). The introduction or delivery for introduction into interstate commerce of adulterated and/or misbranded medical devices is a prohibited act under the Federal Food, Drug, and

Cosmetic Act ("FDCA"), 21 U.S.C. § 331. Those who commit prohibited acts may be subject to injunctions, civil and criminal fines and penalties under 21 U.S.C. §§ 302 and 333. The illegal devices also are subject to seizure under 21 U.S.C. § 304.

Your apparent false and misleading marketing practices and activities also may violate other U.S. federal and state laws and could expose Rebotix and its service centers to significant financial liability. False advertising statements regarding the modified *EndoWrist*® instruments are likely to deceive a substantial segment of your audience with respect to material characteristics of the instruments. The deception caused by such statements – and the attendant potential risk to patient health and safety through the use of modified *EndoWrist*® instruments – threaten to injure or have already injured Intuitive's business and reputation. Such deceptive practices also cause likelihood of confusion or of misunderstanding as to the modified *EndoWrist*® instruments, including but not limited to FDA certification, affiliation with or approval by Intuitive, as well as key characteristics such as safety and effectiveness. You also are liable to the extent your activities interfere with our customers' warranties.

Lastly and most critically, Rebotix's modification of the *EndoWrist*® instruments impacts the intended use of the device, exceeds the verified and validated testing performed by Intuitive to support the FDA 510(k) clearance, and therefore raises serious questions about the safety and effectiveness of the clinical use of such modified instruments in surgical procedures. For this reason, you could face significant financial liability from both practitioners and their patients in connection with your untested, unapproved modification of the *EndoWrist*® instruments.

Demand

Based on the foregoing apparent violations of U.S. law, Intuitive demands that Rebotix and its service centers (and affiliated entities) immediately cease and desist from:

a. marketing and offering a servicing process in the course of which the use counter of *EndoWrist*® instruments' memory device is manipulated and/or replaced to permit more than ten uses; and
b. manipulating and marketing or offering Intuitive's products without FDA clearance of the manipulated products.

Please confirm your compliance with these demands no later than April 30, 2019. If you allege that you or your service centers received FDA clearance for the modifications to the *EndoWrist*® instruments described herein or possess clinical proof that your service process returns the modified instruments to a "production equivalent qualification" and/or that additional use does not affect the safety or performance of the instruments, provide proof of the same no later than April 30, 2019.

We reserve all rights to take all appropriate action against you and to protect Intuitive's rights, products and reputation, including notifying the FDA of these activities for investigation and potential enforcement action against you and pursuing appropriate civil remedies.

Very truly yours,

FOR

Romain Denis
VP, EU and US Regulatory Affairs

Kara Andersen Reiter
SVP, General Counsel & CCO

cc:
R. Reid Haney (Registered Agent), 101 E. Kennedy Boulevard, Suite 3700, Tampa, FL 33602
Rebotix Repair LLC (Street Address), 539 Pasadena Avenue South, St. Petersburg, FL 33707
Benjamin Biomedical (Shared Street Address with Rebotix), 539 Pasadena Avenue South, St. Petersburg, FL 33707